FSIS PERSPECTIVE ON PATHOGEN PERFORMANCE STANDARDS

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Overview

- Previous speakers addressed some of the technical issues surrounding the development and implementation of risk-based performance standards for pathogens, as well as the practicalities of devising consistent, effective, enforceable performance standards.

- I will describe FSIS’s experience in developing pathogen performance standards for both raw and processed meat, poultry, and egg products.
  - How the performance standards were derived
  - How well they appear to be working
  - Lessons learned
  - Future directions
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Pathogen Reduction / HACCP Final Rule

- Issued July 25, 1996
- Established performance standards for *Salmonella* spp. on raw product - carcasses and ground meat and poultry products
- Part of fundamental shift in regulatory philosophy away from command and control type regulations
- Performance standards are a good fit with HACCP
  - Clear objectives for industry to meet
  - Flexibility for industry in how they are achieved
  - Encourage development of new technologies
  - Measurable standards that can be verified by FSIS
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- Performance Standards for *Salmonella* on Carcasses and Raw Ground Product
  - Why FSIS chose *Salmonella* as the target organism for pathogen reduction
  - How the performance standards were derived
  - How FSIS ensured compliance with the performance standards
Why *Salmonella* as the target organism?

- Among the most common causes of foodborne illness associated with meat and poultry
- Methodology exists to detect *Salmonella* in a variety of meat and poultry products
- Serves as a useful indicator of effectiveness of interventions aimed at other enteric pathogens
- Occurs at frequencies high enough so that changes can be detected and monitored
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How Were the Performance Standards Derived?

- Separate standards for carcasses of steers / heifers, cows / bulls, market hogs, and young chickens
- Based on baseline studies which provide a national estimate for the percentage of product that contains *Salmonella*
- FSIS measures compliance with the standard using a series of sample sets. For each product type, FSIS determined the number of samples constituting a set and the maximum number of sample positives that can occur with the establishment still being in compliance
How Were the Performance Standards Derived? (cont.)

- Number of samples per set is greater than 50 for each product type in order to monitor process control over time.
- Number of positives permitted was set so that an establishment that was operating at the performance standard would have an 80% probability of passing the set.
- Performance standard was not derived from a risk assessment or an infectious dose.
- Rather they were based on a judgment that reducing the percentage of product with *Salmonella* would reduce the risk of foodborne illness from enteric pathogens.
- Set so that majority of plants would meet the national average. Some plants would have to improve to come up to the standard.
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How Did FSIS Intend to Ensure Compliance With the Performance Standards?

- Sampling frequency is generally one sample per day. Number of positives in a set is compared to the maximum permitted number for that product category.
- If the establishment exceeds the maximum permitted number of positives, it fails that set.
How Did FSIS Intend to Ensure Compliance With the Performance Standards? (cont.)

- After a sample set failure, the establishment is required to take appropriate corrective actions.
- If the establishment fails a second sample set, it is required to reassess its HACCP plan.
- If the establishment fails a third sample set, FSIS would notify the establishment of its intention to suspend inspection. Third failure constitutes failure to maintain sanitary conditions and failure to maintain an adequate HACCP plan.
- HACCP regulations require the establishment to address in their hazard analysis, hazards that can occur before, during and after entry into the establishment.
Enforcement Strategy Challenged

- Grinding establishment, after third set failure, sued FSIS to prevent suspension of inspection
- Establishment contended that the presence of Salmonella in its ground product was not indicative of the sanitary conditions in the plant, but rather was characteristic of the raw material purchased by the establishment
- Raw material had been inspected and passed by FSIS
- December, 2001 – decision by the U.S. Court of Appeals found in favor of the establishment
Modified Enforcement Strategy

- *Salmonella* set failure triggers in-depth verification of plant’s HACCP system by FSIS.
- Use failure to meet the performance standard as one indicator of overall control
- Failure by the plant to take appropriate corrective action will trigger enforcement action
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Performance Standards in Ready-to-Eat (RTE) Product

- Proposed Rule on Performance Standards for the Production of Processed Meat and Poultry Products (66 FR 12590, February 27, 2001)
  - Lethality performance standards
  - Stabilization performance standards
Proposed Lethality Performance Standards

- For dried, salt-cured, fermented, cooked or otherwise processed whole or comminuted products
  
  Standards expressed as probabilities of remaining numbers of *Salmonella* in 100g of “worst case” product after lethality treatment
  
  Also expressed as number of decimal reductions of *Salmonella* necessary to achieve those probabilities in “worst case” product
  
  *Salmonella* chosen because it has been source of illness outbreaks and has a relatively high heat resistance
  
  “Worst case” product based on high confidence level of the maximum observed level in a national baseline
Proposed Lethality Performance Standards (cont.)

- For fermented product containing beef, also proposing standards for *E. coli* O157:H7
  - Also expressed in terms of probabilities of remaining organisms or log reductions necessary to achieve these probabilities
  - Outbreaks in 1994 and 1995 traced to *E. coli* O157:H7 in fermented beef sausages
Proposed Lethality Performance Standards (cont.)

- For low-acid, thermally processed, commercially sterile product, FSIS proposed to replace the detailed, prescriptive processing requirements with performance standards.
  - Process must result in a probability of $10^{-9}$ or less that there are spores of *C. botulinum* capable of growing, assuming an initial load of $\leq 10^3$ spores/containers.
  - Alternatively, process must achieve a $12 - \log_{10}$ reduction of *C. botulinum*.
Proposed Stabilization Performance Standards

- Prevent multiplication of spore-forming organisms and subsequent toxin formation during cooling of cooked product.
- No multiplication of toxigenic organisms such as *C. botulinum* and no more than $1 - \log_{10}$ multiplication of *C. perfringens*. 
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Role of Performance Standards in HACCP – Based Food Safety Systems

- U.S. Congress (2001) commissioned the NAS to provide recommendations to FSIS and FDA on the role and appropriate use of performance standards for improving food safety

  - Evaluate the scientific basis for the existing performance standards
  - Define the process for establishing food safety criteria
  - Examine whether current criteria accomplish their goals
  - Review the need for performance standards as measures of process control and how they should be used under HACCP
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NAS Report Conclusions and Recommendations

- *Salmonella* pathogen reduction performance standards have achieved their goal of reducing the incidence of salmonellae on meat and poultry
  
  * FSIS observed declines in prevalence of *Salmonella* in meat and poultry products after introduction of Pathogen Reduction / HACCP
  
  * HHS reported a 15% decline in the overall rate of *Salmonella* infections in the U.S. population between 1996 and 2002, based on FoodNet data

- Recommended completion of a new *Salmonella* baseline study in order to determine whether the current performance standards should be revised
NAS Conclusions and Recommendations (cont.)
- Characterized the lethality performance standards as excessively conservative
- Characterized the margin of safety embodied in the stabilization performance standards as too conservative
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- FSIS (2001) charged the NACMCF with providing
  - Advice on the scientific principles for the establishment of performance standards
  - An assessment of the current *Salmonella* performance standards for ground products

NACMCF Conclusions and Recommendations
- Risk must be considered in establishing performance standards in order to link the standard with public health goals
- A risk assessment is needed in order to estimate the impact of the *Salmonella* performance standards on public health
NACMCF Conclusions and Recommendations (cont.)

- A new nationwide baseline study be conducted by FSIS in order to determine whether the current *Salmonella* performance standards for raw ground product need to be revised.

- The reductions in frequency of *Salmonella* positives in FSIS verification samples and the 15% decrease in salmonellosis cases between 1996 and 2001 are indicative of the effectiveness of the pathogen reduction performance standards.
Where Do We Go From Here?

- FSIS will continue to replace prescriptive “command and control” type regulations with performance standards.
- FSIS will conduct new baseline studies on pathogens, including Salmonella and E. coli O157:H7 to use in developing pathogen reduction performance standards.
- FSIS will develop risk – based performance standards for processed products. Rather than using single point, worst case levels, FSIS will use risk assessment to evaluate the public health impact of different performance standards.
Where Do We Go From Here? (cont.)

- FSIS intends to develop lethality and stabilization performance standards for RTE meat and poultry products using risk assessments on *Salmonella* in RTE Product and *C. perfringens* and *C. botulinum* in cooked product after cooling.

- FSIS also intends to develop risk-based performance standards for pasteurized liquid egg products.

- FSIS will address the issue of cross contamination from raw meat, poultry and egg products.
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Summary

- Examples of pathogen performance standards developed by FSIS for both raw and processed meat and poultry products
- Discussed some indicators used to judge how well the standards are working
- Talked about some lessons learned and outlined some future directions